DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 28, 2014

ALPINION MEDICAL SYSTEMS Co., Ltd.
% Mr. Donghwan Kim
QARA Manager
1, 6 and 7FL Verdi Tower, 72,
Digital-ro(St) 26-gil(Rd), Guro-gu
Seoul 152-848
REPUBLIC OF KOREA

Re: K142884
Trade/Device Name: E-CUBE 12
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: September 30, 2014
Received: October 2, 2014

Dear Mr. Kim:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the E-CUBE 12 Diagnostic Ultrasound System, as described in your premarket notification:

Transducer Model Number

SC1-4H SC1-6 L3-12 L3-12H SP1-5

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142884

Device Name
E-CUBE 12 Diagnostic Ultrasound System

Indications for Use *(Describe)*
The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric, Small Organ (breast, testes, thyroid); Adult Cephalic; Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Cardiac (adult& pediatric); Peripheral Vascular (PV); and Urology (including prostate).

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Food and Drug Administration
Office of Chief Information Officer
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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Diagnostic Ultrasound Indications for Use

E-CUBE 12 Ultrasound System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (Specify)**	**Other** (Specify)**
Ophthalmic									
Fetal	N	N	N		N	N	N	N	
Abdominal	N	N	N		N	N	N	N	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	N	N	N		N	N	N	N	
Small Organ (breast, testes, thyroid)	N	N	N		N	N	N	N	
Neonatal Cephalic									
Adult Cephalic	N	N	N		N	N	N	N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)	N	N	N		N	N	N	N	
Musculo-skeletal (***Superficial***)	N	N	N		N	N	N	N	
Intravascular									
Cardiac Adult	N	N	N		N	N	N	N	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	N	N	N		N	N	N	N	
Urology (including prostate)	N	N	N		N	N	N	N	

N = new indication; P = previously cleared by FDA; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 12 with SC1-4H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (Specify)**	**Other** (Specify)**
Ophthalmic									
Fetal	P	P	P		P	P	P	P	
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K 121888; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 12 with SC1-6 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (Specify)**	**Other** (Specify)**
Ophthalmic									
Fetal	P	P	P		P	P	P	P	
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)	P	P	P		P	P	P	P	

N = new indication; P = previously cleared by FDA K111864; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 12 with L3-12 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (Specify)**	**Other** (Specify)**
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)	P	P	P		P	P	P	P	
Musculo-skeletal (***Superficial***)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K111864; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

Diagnostic Ultrasound Indications for Use

E-CUBE 12 with L3-12H Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (Specify)**	**Other** (Specify)**
Ophthalmic									
Fetal									
Abdominal									
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)	P	P	P		P	P	P	P	
Neonatal Cephalic									
Adult Cephalic									
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)	P	P	P		P	P	P	P	
Musculo-skeletal (***Superficial***)	P	P	P		P	P	P	P	
Intravascular									
Cardiac Adult									
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel	P	P	P		P	P	P	P	
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K111864; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH

Diagnostic Ultrasound Indications for Use

E-CUBE 12 with SP1-5 Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application	Mode of Operation								
	B	**M**	**PWD**	**CWD**	**Color Doppler**	**Power Doppler**	**Tissue Harmonic Imaging**	**Combined* (Specify)**	**Other** (Specify)**
Ophthalmic									
Fetal									
Abdominal	P	P	P		P	P	P	P	
Intra-operative (Specify)									
Intra-operative (Neuro)									
Laparoscopic									
Pediatric	P	P	P		P	P	P	P	
Small Organ (breast, testes, thyroid)									
Neonatal Cephalic									
Adult Cephalic	N	N	N		N	N	N	N	
Trans-rectal									
Trans-vaginal									
Trans-urethral									
Trans-esoph. (non-Card.)									
Musculo-skeletal (***Conventional***)									
Musculo-skeletal (***Superficial***)									
Intravascular									
Cardiac Adult	P	P	P		P	P	P	P	
Cardiac Pediatric									
Intravascular (Cardiac)									
Trans-esoph. (Cardiac)									
Intra-cardiac									
Peripheral vessel									
Urology (including prostate)									

N = new indication; P = previously cleared by FDA K111864; E = added under appendix

* Combined: B/Color Doppler, B/PWD, B/Color Doppler/PWD; **Other: 3D, 4D

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Concurrence of CDRH

Prescription User (Per 21 CFR 801.109)

Section F 510(k) Summary

In accordance with 21CFR807.92, the following summary of information is provided;

Date	Sep 19th 2014
Submitter:	ALPINION MEDICAL SYSTEMS Co., Ltd. Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848
Primary Contact Person	Donghwan Kim QARA Manager Address: 1, 6 and 7FL Verdi Tower, 72, Digital-ro(St) 26-gil(Rd), Guro-gu, Seoul, Republic of Korea 152-848 Phone: +82 70 7465 2068 Fax: +82 2 851 5594 Email: donghwan.kim@alpinion.com
Secondary Contact Person	JULIAN LEE Address: 21312 30th Dr SE Ste 100 Bothell, WA 98021, United States Phone: 425 949 1059 Fax: 425 949 4910 Email: julian.lee@alpinionusa.com
Device Trade Name:	E-CUBE 12
Common/Usual Name:	Ultrasonic Pulsed Doppler Imaging System
Classification Names	System, Imaging, Pulsed Doppler Ultrasonic
Product Code:	Ultrasonic Pulsed Doppler Imaging System, 21CFR 892.1550 90-IYN Ultrasonic Pulsed Echo Imaging System, 21CFR 892.1560, 90-IYO Diagnostic Ultrasound Transducer, 21CFR 892.1570, 90-ITX
Predicate Device(s)	K123610 E-CUBE 15 Diagnostic Ultrasound System
Device Description:	E-CUBE 12 product is an ultrasound imaging system for medical diagnosis. The system platform provides optimal patient diagnosis workflow with the 21.5” wide flat panel display, ergonomic control panel with easy user interface, optimal image quality. Modes of operation: **1. Signal Mode**: B(2D) mode, M mode, Color Flow(CF) mode, Power Doppler(PD) mode, Pulsed Wave Doppler(PWD) mode, Tissue Harmonic Imaging(THI) **2. Combination Mode:** B/M, B/CF, B/PD, B/PWD, B/CF/PWD, B/PD/PWD, B/CF/M Acoustic output track: Track 3

Types of transducers compatible with the device:

	SC1-4H	SC1-6	L3-12	L3-12H	SP1-5
Applicable frequency	1~4MHz	1~6MHz	3~12MHz	3~12MHz	1~5MHz
Intended Usage	Fetal, Abdominal, Pediatric, Urology	Fetal, Abdominal, Pediatric, Urology	Pediatric, Small Organ, Musculoskeletal (conventional & superficial), Peripheral vessel	Pediatric, Small Organ, Musculoskeletal (conventional & superficial), Peripheral vessel	Abdominal, Pediatric, Cardiac Adult
Foot print size (mm)	72.4 x 16.8	72.4 x 16.8	44.8 x 7.8	44.8 x 7.8	24.8 x 17.6
Applicable mode	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging	B/M/PWD/ Color Doppler/ Power Doppler	B/M/PWD/ Color Doppler/ Power Doppler	B/M/PWD/ CWD/ Color Doppler/ Power Doppler/ Tissue Harmonic Imaging
Scanning depth(mm)	300	300	100	100	300
FOV	60(°)	60(°)	N/A	N/A	90(°)
Steer Angle	N/A	N/A	Max 9(°)	15(°)	45(°)
Geometrical configuration	Curved linear array 60mm Radius of curvature	Curved linear array 60mm Radius of curvature	Linear array 38.4mm aperture	Linear array 38.4mm aperture	Linear phased array
Total number of element	192	128	128	192	64
Element spacing	0.342mm	0.484mm	0.3mm	0.2mm	0.3mm
elevating length	13.5mm	13.5mm	4.5mm	4.5mm	13.5mm

Indications For Use: The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric, Small Organ (breast, testes, thyroid); Adult Cephalic; Musculo-skeletal (Conventional); Musculo-skeletal (Superficial); Cardiac (adult& pediatric); Peripheral Vascular (PV); and Urology (including prostate).

Technology: E-CUBE 12 employs the same fundamental scientific technology as its predicate device.

Determination of Substantial Equivalence: Comparison with Predicate device:

Feature	Proposed E-CUBE 12	Predicate E-CUBE 15 (K123610)

Indications for use	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Adult Cephalic; Musculo-skeletal(Conventional); Musculo-skeletal Superficial); Cardiac (adult & pediatric); Peripheral Vascular (PV); Urology (including prostate).	The device is intended for use by a qualified physician for the evaluation of soft tissue and blood flow in the clinical applications; Fetal; Abdominal (renal & GYN/pelvic); Pediatric; Small Organ (breast, testes, thyroid); Trans-rectal(TR); Trans-vaginal(TV); Musculo-skeletal (Conventional) Musculo-skeletal (Superficial) Cardiac (adult & pediatric); Peripheral Vascular (PV); Urology (including prostate).
Transducer	SC1-4H SC1-6 L3-12 L3-12H SP1-5	SC1-4H SC1-6H SVC1-6 L3-12H L3-12X L3-8 L8-17X SP1-5X SP3-8 E3-10H CW2.0 CW5.0
Electrical power	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board Peripherals	Voltage: 100~120V, 200~240V Frequency: 50/60Hz Power: Max. 900 VA with Built-in and On-Board Peripherals
Operating Mode	B(2D) Mode M Mode Color Flow (CF) Mode Power Doppler (PD) Mode Pulsed Wave Doppler (PWD) Mode Tissue Harmonic Imaging (THI) Mode Beam Steering Spatial Compounding Frequency Compounding Xpeed™ Auto traces PW Directional Power Doppler Mode SRI Full SRI™	B Mode M Mode Color Flow (CF) Mode Power Doppler (PD) Mode Pulsed Wave Doppler (PWD) Mode Continuous Wave (CW) Doppler Mode Tissue Harmonic Imaging (THI) Mode 3D/4D Volume Mode Beam Steering Panoramic B/CF Spatial compounding Frequency compounding Xpeed on 2D / CF/PW Auto IMT Auto traces PW Directional Power Doppler Mode SRI Full SRI ECG

Thermal, mechanical and electrical safety	The E-CUBE 12 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37	The E-CUBE 15 has been designed to conform to the following standards: - NEMA UD2, UD3 - AIUM Medical Ultrasound Safety - IEC60601-1 - IEC60601-1-2 - IEC60601-2-37

Summary of Non-Clinical Tests:

E-CUBE 12 has been evaluated for biocompatibility, acoustic output as well as thermal, electrical, electromagnetic, and mechanical safety, and has been found to conform to applicable medical device safety standards. E-CUBE 12 and its application comply with voluntary standards as detailed in this premarket submission. The following quality management system measures were applied to the development of E-CUBE 12:

- Medical Device Risk Management
- Requirements Reviews
- Design Reviews
- Component Verification
- Integration Review (System Verification)
- Performance Testing (System Verification)
- Safety Testing (Compliance Test)
- Design Validation

Transducer materials and other patient contact materials are biocompatible.

Summary of Clinical Tests:

The subject of this premarket submission, E-CUBE 12, did not require clinical studies to support substantial equivalence.

Discussion:

E-CUBE 12 and the predicate device have differences in clinical applications and operating modes. Several transducers are changed for these purposes. These design changes have been verified via non-clinical testing. The subject device is in conformance with applicable safety standards. Therefore, the differences between E-CUBE 12 and the predicate would not affect the safety, effectiveness and essential performance of E-CUBE 12.

Conclusion: ALPINION MEDICAL SYSTEMS Co., Ltd. considers E-CUBE 12 to be as safe, as effective. Performance, technology and software are substantially equivalent to the predicate device.

ALPINION MEDICAL SYSTEMS Co., Ltd. will update and include in this summary any other information deemed reasonably necessary by the FDA or the requirements will be published in guidance documents.